[1]Agreement[2]
between National Authorities responsible[3] for
National Contact Points for eHealth
on the Criteria[4] required for the participation in
Cross-Border eHealth Information Services

eHealth Network

JAseHN Task 6.2

Draft v.**2**, 20.10.2016

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[1] The footnotes in the document serve clarification during drafting and review process but will not be contained in the final version of the Agreement.

[2] The notion "MLA" has led to misunderstandings regarding its nature (international treaty, contractual agreement, administrative/executive agreement etc.) whereas MLA means nothing more than a "Legal" (i.e. binding) "Agreement" between more than two Contracting Parties ("Multilateral") which can have any of the above natures, depending on how its content fits into respective national law. Therefore, the Agreements' nature must, strictly legally spoken, be assessed by each Contracting Party under its own national law which thus might even have different outcomes for different Contracting Parties. However, what we actually have always been working on with our "directive method", aiming at non-interference with national law, is an "administrative agreement" because it would ideally be signed at ministerial and thus administrative level but neither higher (in order to strictly avoid an international treaty with time-consuming ratification procedures) nor lower (for the sake of stability). Even by following the suggested approach, there might be MS' constitutional laws still requiring national coordination and/or ratification via involvement of other ministries and/or parliament. However, the above approach seems to be all that the drafting team can propose for ensuring the Agreement's timely adoption.

It was requested to delete "Administrative" for even less interfering with national law.

The possibly required signature of the Agreement by the eHDSI solution provider/EC as Contracting Party (see below Section 3: Semantic criteria) could have serious implications for the Agreement's nature and will therefore be considered only after a final and official decision upon the entity responsible for the operation and maintenance of semantic central (core) services under the eHDSI has been taken.

[3] For the same reason of strictly avoiding an international treaty, the drafting team has discussed the (legal) possibility of having the Agreement signed by the national competent authorities running (operating) the NCPeH. In accordance with our "directive method", aiming at non-interference with national law, the Agreement would not prescribe (and thus leave to Contracting Parties) WHICH competent authority shall run the NCPeH. However, the question is whether all competent authorities operating the NCPeH are ALLOWED under respective national law to sign the Agreement – and it seems that there are some having a problem with this delegation of competence to e.g. agencies. Therefore, it is suggested to sign the Agreement between National Authorities responsible for NCPeH – ideally at administrative level.

[4] These "criteria" relate to all LOST criteria (legal, organisational, semantic and technical); see Sections 1-4 under Chapter II.

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Glossary of abbreviations and definitions

CBeHIS	Cross-Border eHealth Information Services as agreed by the eHN, e.g. Patient Summary
Contracting Party	National Authority responsible for NCPeH in a Member State of the EU or EFTA that has signed this Agreement
Country A	Member State of affiliation according to Art. 3 (c) of Directive 2011/24/EU
Country B	Member State of treatment according to Art. 3 (d) of Directive 2011/24/EU
Cross-border healthcare	Term as defined in Art. 3 (a) and (e) of Directive 2011/24/EU[5]
EFTA	European Free Trade Association
eHN	eHealth Network according to Article 14 of Directive 2011/24/EU
EU	European Union
Governing body	[6]
Healthcare provider	Term as defined in Art. 3 (g) of Directive 2011/24/EU
Health professional	Term as defined in Art. 3 (f) of Directive 2011/24/EU
National Authority responsible for NCPeH	Ministry responsible for eHealth, or an organization at a lower level to which the competence of either operating the NCPeH and/or signing this Agreement was demonstrably delegated by the Ministry responsible for eHealth, or an Authority at an even higher level than the Ministry responsible for eHealth (e.g. Government as collegial organ) as required by the national laws and procedures of a Contracting Party
NCPeH	National Contact Point for eHealth, acting as organisational and technical gateway for the provision of CBeHIS

[5] NB: Art. 3 (e) seems to be wrong for ePrescription.

[6] Refers to either eHN sub-group comprised of Contracting Parties or eHMSEG or eHOMB, as agreed by the eHN, depending on the revised Governance model for the eHealth Digital Service Infrastructure during the CEF funding – once this revised model is agreed, the Governing Body for the purpose of this Agreement can be further specified.

Chapter I
General objective and scope[7]

Clause I.1

(1) The eHealth Network (eHN) set up under Article 14 of Directive 2011/24/EU is the main political and strategic Governance Body for eHealth in Europe, connecting the National Authorities responsible for National Contact Points for eHealth (NCPeH). The eHN has the mandate to establish an European Interoperability Framework for Cross-Border eHealth Information Services (CBeHIS) with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare.

(2) Whereas organisational, semantic and technical interoperability have been worked upon by the eHN, the creation of legal interoperability is another prerequisite for the achievement of the objectives under Articles 11 and 14 of Directive 2011/24/EU. This requires an even closer cooperation among the Contracting Parties by way of displaying the legal criteria laid down in EU law and the Contracting Parties' national laws, and furthermore referring to the organisational, semantic and technical criteria, as agreed by the eHN and to be adhered to[8] for the purpose of providing CBeHIS.

(3) This Agreement thus defines the criteria for the processing of personal data concerning health for the purpose of cross-border healthcare according to Directive 2011/24/EU by means of the CBeHIS.

Clause I.2

(1) Ensuring continuity of cross-border healthcare depends on transmission of personal data concerning patients' health. These personal data should flow[9] from one Contracting Party to another, while at the same time the fundamental rights of the patients shall be safeguarded.

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[7] In the last MLA version (2016-06-11), the "Preamble" was re-named into "Recitals" as the former naming is too closely linked with international treaties which must be avoided due to time-consuming ratification procedures. But as "Recitals" point at a legislative act which is even less desirable, it is suggested to have no Preamble or Recital at all but instead only a Chapter I, defining the "General objective and scope". Again: everything pointing towards an international treaty must be strictly avoided. The introductory Chapter I will be revised and updated, based on the overall text once it has been more elaborated.

[8] It is impossible to make the existing Guidelines in the Annexes strictly legally binding due to their nature and content as well as the techncial complexity of CBeHIS (see therefore "processes and criteria" under Clause III.1.2.1). As it can be seen from the Annex, the drafting team has to deal with many uncertainties in terms of the detailed processes and criteria for the Contracting Parties' admission to participate in CBeHIS, especially regarding Annexes 8, 9 and 10. The drafting team will be in close contact with the authors of these documents in order to reflect all legal, organisational, semantic and technical criteria in the Legal Agreement and vice-versa. The difference of the mentioned Guidelines and the further "guidance" (on data protection as well as liability, applicable law and jurisdiction) to be elaborated by the drafting team is that the latter, as stated in the Agreement's text, "may" be used by the Contracting Parties and are therefore not binding in any parts because the relevant criteria are already set forth in EU and national law.

[9] The words "be able to" were deleted (as a matter of wording).

(2) This requires that each Contracting Party of a Country A provides the patient with adequate, correct and up to date information about the transmission of his or her personal data to a Contracting Party of a Country B, together with ensuring the secure transmission of the data to this Contracting Party of a Country B.
(3) Each Contracting Party of a Country B shall ensure secure receipt of this data and provide the appropriate level of protection when data is processed, in conformity with national law implementing[10] Union provisions on the protection of personal data, in particular Regulation 2016/679/EU[11], and also ensure the secure transmission of data to the Contracting Party of a Country A.

Clause I.3

(1) Contracting Parties to this Agreement may[12] be the National Authorities responsible for NCPeH in Member States of the EU and EFTA.[13]
(2) All National Authorities are free to choose whether to participate in the signature of this voluntary Agreement, depending on which CBeHIS they wish to offer as a Contracting Party of a Country A and/or Country B.[14]

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[10] It was proposed to delete "national law implementing", arguing that "*it is essential not to interfere with national law*". Since this was not further explained while implementing national law as a minimum level of protection is conditio sine qua non for mutual recognition as the Agreement's central pillar, this proposal cannot be accepted.

[11] Regulation 2016/679/EU will replace the current Directive 95/46/EC as from 25.5.2018. The real data exchange under CEF might already start before 25.5.2018 but realistically only afterwards. Therefore, it is suggested for now to refer only to Regulation 2016/679/EU and eventually modify (via additional references to the Data Protection Directive 95/46/EC e.g. in footnotes) if exchange is foreseeable before 25.5.2018.

[12] It was proposed to replace "may" with "shall". Since this proposal was not explained and the Agreement is voluntary, this proposal cannot be accepted.

[13] On Clause I.3(1), the following comment was made:

"*It is object to proof for national law whether it is enough for national authorities responsible for the NCPeH to sign or whether it is considered to be a international treaty, whereas the respective member state would be contracting party.*"

Indeed, as stated already in the first footnote in this document, the Agreements' nature must, strictly legally spoken, be assessed by each Contracting Party under its own national law which thus might even have different outcomes for different Contracting Parties. With regard to the linked question on who may sign the Agreement, the above concerns are considered in the above proposal for a definition of "National Authority responsible for NCPeH" as Contracting Parties.

[14] The following proposal was made on Clause I.3(2):

1. *The formulation suggests that member states can choose the level of commitments to this agreement.*
2. *We suggest to avoid going into details about country A or B. We need to keep a level of generality in order to simplify the agreement.*

We propose the following formulation :

3. *"Member States are free to implement the CBeHIS. If they decide to enter these services, they can choose for which use cases they decide to operate.*
4. *Once these choices have been made, the signature of this agreement consists the first step of the go-live for the process.*

This proposal is considered as follows:

(3) Once a National Authority has chosen to become a Contracting Party to this Agreement, it is obliged to fulfil the criteria required herein in order to be admitted to participate in the CBeHIS according to paragraph (2). All Contracting Parties have the right to choose, in accordance with EU law and their respective national law, the method for the fulfilment of the required criteria.[15]

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1. In order to further clarify, as already done in the following para. (3), that Contracting Parties cannot choose the level of commitments, the words ”and to what extend” are deleted.
2. The distinction between (Contracting Party of a) Country A and/or Country B is necessary because firstly it corresponds to the structure and provisions of Directive 2011/24/EU and secondly the Contracting Parties' obligations under Regulation 2016/679/EU depend on it.
3. In order to keep a level of generality as proposed under point 2., the proposed statement is already contained in the formulation of para. (2).
4. ”Go-live” is no legal wording and the sequencial steps leading to an admission by eHN are contained in Chapter III (Governance and rules of procedure) and the “Policy paper on assessment and decision procedures under CEF funding” contained in the annexed “List of referred documents”.

[15] The following proposal was made on a (additional) Clause I.3(4):

EFTA and EU Contracting Parties are committed to accept personal health data flows from EU member states under two conditions:

- they need to formalize at the right level their acceptance and compliance with applicable European legislation and rules.

- they need to sign this agreement;

Since this proposal

- was not further explained,

- there are more than only two conditions (stated in the rest of the Agreement).

- is not in accordance with the wording of Regulation 2016/679/EU (“*personal health data flows*”),

- is not consistent in itself (“*from EU*” only or also EFTA? Why mentioning “*member states*” when trying to avoid an international treaty?),

- the signature of the Agreement and further sequencial steps leading to an admission by eHN will be contained in Chapter III (Governance and rules of procedure) and/or the “Policy paper on assessment and decision procedures under CEF funding” and

- “*accept personal health data flows”* in the legal text would raise unnecessary tensions (all the more so as the similar statement in Clause I.2[1] “*These personal data should be able to flow from one Contracting Party to another*” was, at the same time, proposed to be deleted),

it cannot be accepted.

Chapter II
Criteria required for the participation in CBeHIS

Section 1: Legal criteria

Clause II.1.1

Data protection and security

Clause II.1.1.1
Legal basis for the cross-border processing and patient information
(1) The processing of personal data concerning health for the purpose of cross-border healthcare pursuant to Directive 2011/24/EU is lawful according to national law compliant with the conditions stated in Regulation 2016/679/EU, in particular Article 9 thereof. Contracting Parties may use the further guidance on data protection[16].[17]
(2) Patients must be provided by the Contracting Party of a Country A with the information pursuant to Articles 13 and 14 of Regulation 2016/679/EU, including information on the institutions involved in the further processing of the data in a Country B. Contracting Parties may use the model patient information notice[18].[19]

[16] The guidance on data protection will be set out in a separate document because it will not have the same status as other documents in the annexed "List of referred documents".

[17] Art. 8(2) of Directive 95/46/EC ("or") and Art. 9(2) of Regulation 2016/679/EU ("if one of the following applies") state lawful grounds for processing personal health data alternatively. The Art. 29 WP189 on epSOS, requiring two-steps consent, has some important caveats as explained in the further guidance on data protection set out in Annex 2. The Contracting Parties may well foresee consent as their lawful ground for CB-processing, but the Legal Agreement must not require consent as the only lawful ground since this would interfere with EU law (see above) and also national law, with special regard to the Legal Agreement's timely adoption and sustainability. The Art. 29 Working Party cannot reasonably be contacted before having a consolidated opinion on data protection from EC (including DG JUST and Legal Service) and also the technical details of the exchange (operationalizing the data protection requirements) will be set in place by the eHDSI solution provider. The drafting team and EC will consider informal consultations with the Art. 29 Working Party. In parallel, all members of T6.2 should consult at national level with their representatives (former DAPIX members) in the expert group on the implementation of Regulation 2016/679/EU that was recently set up by EC/JUST.

[18] The model patient information notice will be set out in a separate document because it will not have the same status as other documents in the annexed "List of referred documents".

[19] This model patient information notice (to be set-up on a website) will be elaborated at a later stage, complementing the further guidance on data protection set out in Annex 3. All members of T6.2 will internally consider their respective "institutions involved in the further processing" in order to provide this information for the elaboration of the model patient information notice.

Clause II.1.1.2

Identification and authentication of patients, health professionals and healthcare providers[20]

(1) In order to enhance patient safety and privacy in cross-border healthcare, Contracting Parties shall ensure the unambiguous[21] identification of patients, health professionals and healthcare providers:

a.) Contracting Parties using electronic means of identification that are notified under Regulation 2014/910/EU and applicable to the health domain, shall adhere to this Regulation and its Implementing Acts.

b.) Contracting Parties using non-electronic means of identification, or using electronic means of identification not notified under Regulation 2014/910/EU, or using electronic means of identification that are notified under Regulation 2014/910/EU but not applicable to the health domain, shall adhere to the relevant document listed in the Annex[22].

[20] Current state on identification & authentication encompass (1) MSs that do not have an eID system (i.e. non-e)ID, (2) MSs that will notify an eID system under eIDAS Regulation that applies to the health domain, (3) MSs that have an eID system but may not notify under eIDAS Regulation and (4) MSs that notify an eID system which however does not apply to the health domain. All these four cases must be considered under Clause II.1.1.2.

eIDAS Regulation will only apply to MSs notifying an eID system (i.e. mutual recognition). A further specification of eIDAs Regulation for the health domain is needed in terms of Levels of Assurance and attributes for health professionals. This task has been assigned to JAseHN T5.2 with the elaboration of the **JAseHN D5.2.1 (eID specific Framework for eHealth) which has not yet been adopted. But even if adopted by the eHN, it must still be decided amongst the Contracting Parties if they wish to agree on these eHealth specifications on eID for the purpose of the Agreement.**

eIDAS Regulation will not apply to the cross-border healthcare exchange if one of the Contracting Parties either does not notify its eID System or notifies an eID system that cannot be applied to health domain. Those cases must be solved by either notifying under eIDAS Regulation or using an ambiguous identification. **Therefore, it must be decided amongst Contracting Parties if the (voluntary) notification under eIDAS Regulation should be required from Contracting Parties under this Agreement and/or if Contracting Parties that notify their electronic means of identification under the eIDAS-Regulation intend to recognise those of other Contracting Parties not notified under eIDAS-Regulation or notified but at a lower level of assurance.**

[21] A unique identifier would be desirable to be requested from all Contracting Parties for the identification and authentication processes for the sake of patient safety. However, the variety of identification systems makes it impossible to request this unique identifier (some MSs have a unique cross-sector ID, other MSs have a unique health sector ID, others just have an unambiguous ID system composed of a set of attributes). However, in order to ensure patient safety on a minimum level, Contracting Parties would be requested to provide at least an unambiguous identification of patients.

[22] The document ”Mandatory attributes used by Contracting Parties acting as Country A for the unambiguous identification of patients” listed in the Annex will include mandatory attributes used by Contracting Parties of Country A for the unambiguous identification of patients. Process to be followed by health professional of Country B, shall encompass two essential steps:

1.) Choosing the respective Country A.

2.) Entering the data into mandatory fields stated in this Annex by Contracting Parties of Country A.

(2) Each Contracting Party shall ensure that it uses means of authentication that are adequate to the sensitivity of personal data concerning health according to Regulation 2014/910/EU and Regulation 2016/679/EU.[23]

Clause II.1.1.3

Authorization of health professionals[24]

Each Contracting Party of a Country B shall ensure that for the purpose of cross-border healthcare and without prejudice to other lawful grounds for processing under Regulation 2016/679/EU, only health professionals[25] authorized according to its national law may have access to patients' data concerning health.

[23] The separation of para.2 (authentication) from para.1 (identification) takes into account that identification and authentication may be simultaneous or separate processes, depending on the system used.

[24] MS are competent to define which health professionals with specific roles may process personal data concerning health, since this concept has different meanings in different MS (e.g. nurses, nurse aid, etc.). Therefore, each Contracting Partiy of Country B shall be responsible to grant privileges for data processing to health professionals.

[25] Contrary to Clause II.1.1.2 on identification and authentication, it was agreed to not also mention healthcare providers in Clause II.1.1.3 on authorization because if e.g. hospitals or pharmacies act as organisations, their (internal) authorization of health professionals must also be done "according to national law".

Clause II.1.2

Liability, applicable law and jurisdiction[26]

Clause II.1.2.1

Civil Liability[27]

The substantive grounds for liability[28] are determined by the relevant national law.[29] The jurisdiction and applicable law for liability claims is determined by the EU law in accordance with Clauses II.1.2.3 and II.1.2.4 below.

Clause II.1.2.2.

Liability between the Contracting Parties

(1) Contracting Parties are liable towards each other for any damage resulting from the infringement of the criteria required under this Agreement.

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[26] It was proposed to delete – apart from the reference to the (non-binding) further guidance on liability, applicable law and jurisdiction – the whole, rather descriptive Clause II.1.2 and replace it by the following sentence:

"*The civil liability of the NCPeHs is determined by the liability regime for public bodies in accordance with the law of their own Member State.*"

This proposal will have to be duly considered in cooperation with EC/DG JUST and also depend on the necessity of using non-repudiation/formal-acceptance for the purpose of jurisdiction beyond the above case of NCPeH liability.

[27] The foreseen civil liability scenarios concern mainly health professionals and NCPeHs towards patients:

1) Medical liability, e.g. patient's damage claim against a healthcare professional/hospital/pharmacy;

2) False identification

3) Data breaches, e.g. access to data granted to unauthorised persons;

4) Translation errors

NB: The liability may also be determined on a contractual basis (treatment contract, insurance contract).

[28] I.e. strict/fault-based liability, causal link, definition of the damage, level of compensation etc.

[29] For the purposes of the **medical liability**, the CBHC Directive (2011/24/EU) requires all Member States to have:

- systems of professional liability insurance (or equivalent) in place for treatment provided in their territory (Article 4(2)(d)).

- transparent complaint procedures and mechanisms for patients to seek remedies in accordance with the legislation of MS of treatment if they suffer harm arising from healthcare they receive (Article 4(2)(c)).

For the purposes of the liability for **data breaches**, Article 82 of the GDPR grants a right to receive compensation from the controller or processor for either material or non-material damage as a result of infringement of the Regulation. There are also rules to ensure compensation in case of breaches by several controllers or processors involved in the same processing (Article 82(4) and (5).

(2) Rules of creation of evidence stated in Clause II.4.2 shall be used to determine the responsible actor for the purposes of jurisdiction and applicable law.

Clause II.1.2.3

Applicable Law

(1) In case of legal civil claims,[30] the applicable law is determined by the Regulation 593/2008 (Rome I) and Regulation 864/2007 (Rome II).[31]

(2) In case of claims brought against public authorities acting in their public capacity or exercising state authority, the applicable law is determined by the rules of private international law of that state.[32]

Clause II.1.2.4

Jurisdiction

(1) In case of legal civil claims,[33] the competent jurisdiction is determined by the Regulation 1215/2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Brussels I).[34]

(2) In case of claims brought against public authorities acting in their public capacity or exercising state authority, the applicable law is determined by the rules of private international law of the Contracting Parties.

(3) The competent jurisdiction for an effective remedy for breach of the Regulation 2016/679/EC is determined by its Article 79(2).[35]

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[30] E.g. between the patient and a private healthcare provider.

[31] The applicable law under these rules is normally either the patient's domicile or the place of treatment. It depends on a number of factors that may only be determined case-by case, e.g. whether there is a contractual relationship or not, or whether the country of residence of the patient is the same as that of the service provider (e.g. pharmacy/doctor). The Contracting Parties may also agree on applying another law after the event giving rise to the damage occurred. Further guidance on these aspects maybe developed for our use scenarios, but it needs to be kept in mind that each case needs to be decided on its own facts and merits.

[32] This clause is important for the **NCPeH liability**. NCPeHs are normally expected to exercise public powers. The liability of public bodies is harmonized within the EU only to the extent damage is caused by a violation of the EU law. In this exceptional case the main grounds of liability (serious breach, causality, damage) are determined by the EU law under the so-called Francovich case law. Otherwise, the civil liability of the NCPeHs is determined by the liability regime for public bodies in accordance with the law of their own Member State.

[33] E.g. between the patient and a healthcare provider.

[34] The main rule is the place of defendant's domicile (Article 4). In our use cases the defendant for medical liability may be either the doctor/health professional who prescribed the medicine (in this case the law of country A would apply), or the dispensing pharmacy (in this case the law of country B would apply). This main rule covers all private law disputes arising from either medical or other kind of private liability claims relating to the chain of operators in data handling from country A to country B. The grounds for liability (fault-based/objective etc) are not harmonised by EU law. Therefore these issues are determined by the rules of the national law the choice of which is determined according to the application of the above EU Regulations.

Contracting Parties may use the further guidance on liability, applicable law, jurisdiction[36].[37]

Section 2: Organisational criteria

Clause II.2
Processing of personal data concerning health via NCPeH

Each Contracting Party shall designate one NCPeH to act as a single communication gateway with the NCPeH designated by other Contracting Parties. In order to be admitted to participate in the CBeHIS according to the process defined under Clause III.1.2.1 of this Agreement, each Contracting Party shall ensure the compliance of its NCPeH with the criteria set forth in this Agreement, taking into account the relevant processes and criteria defined in the documents that are referred to in the Annex.

[35] "Proceedings against a controller or a processor shall be brought before the courts of the MS where the controller or processor has an establishment. Alternatively, such proceedings may be brought before the courts of the Member State where the data subject has his or her habitual residence, unless the controller or a processor is a public authority of a Member State acting in the exercise of its public powers."

[36] The guidance on liability, applicable law, jurisdiction will be set out in a separate document because it will not have the same status as other documents in the annexed "List of referred documents".

[37] The further guidance, as stated in the above footnotes, on liability, applicable law, jurisdiction will contain basically what is now stated in the footnotes under Clause II.1.2, though fine-tuned in collaboration with EC/JUST. For this purpose, Dr. Georg Haibach from EC/JUST attended the meeting of T6.2 on 11.10.2016 where he kindly agreed to support the drafting team.

Section 3: Semantic criteria[38]

Clause II.3
Semantic transformation[39]

(1) Each Contracting Party shall ensure semantic transformation as needed for cross-border healthcare via CBeHIS.[40]

(2) Each Contracting Party is responsible for the accuracy and integrity of semantic processing and must therefore use the latest version of the Master Value Set Catalogue[41] and maintained national versions of these controlled vocabularies used in semantic transformation.

(3) Each Contracting Party is liable towards Patients and other Contracting Parties according to Clause II.1.2 for any damage resulting from errors in semantic transformation[42].[43]

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[38] Povided that the eHDSI solution provider/EC will indeed operate and maintain semantic central (core) services as necessary for the provision of CBeHIS, it must be held liable for the performance of the central services (including IP rights) and also for possible errors occurring within these services. Consequently, the eHDSI solution provider/EC would also need to be a Contracting Party to the Agreement. Therefore, the legal work depends on a final and official decision on the entity responsible for the operation and maintenance of semantic central (core) services under the eHDSI.

[39] The existing Guidelines do not cover more than stated in the following on semantic transformation, especially on standards to be used. A task force under eHMSEG was created in order to address this topic. Therefore, it might be necessary to additionally refer to a relevant Annex, once details are more clear.

[40] Each Contracting Party needs appropriate license arrangements for the right to use the necessary standard coding systems. Since this is a prerequisite for the needed performance of semantic transformation and thus implied in paragraph (1), it is suggested to not state this expressively.

[41] It is to be acknowledged that the MVC is currently the only solution and therefore taken for drafting this Clause.

[42] Semantic transformation consists of two activities: Firstly NCPeH/A transforms the original data (in code A and language A) into a new document (in common codes and in common language). Secondly NCPeH/B transforms the obtained document into code B and language B, before transmitting it to the physician/B. Therefore both NCPeH/A and B can commit errors in semantic transformation, thus causing various possible damages.

In the case of Malta, since the standard language for health records in Malta is English and the ”common language” is English, there are cases where translation/transformation is not required. Moreover, Malta’s technical approach to date has envisaged that for the NCPeH/A case transcoding is carried out within the national infrastructure, i.e. before the data reaches the NCPeH. Therefore, Clause II.3 is re-formulated in a broader way by not referring to NCPeH. Subject to objections from a technical perspective, the Contracting Parties’ obligations on semantic transformation remain the same also without explicit reference to NCPeH.

[43] The (General) Guidelines on Electronic exchange of health data under the Cross-Border Directive 2011/24/EU provide in Article 6(2) that ”[i]n the event of semantic transformation, both the transformed and the original documents shall for safety and audit reasons be available to all persons who are authorised to use this data.” So far it could be clarified that the authorisation refers primarily to HP according to respective national law. But the exact background still needs to be clarified, especially if accessing both documents is required also for patients and for purposes beyond safety and audit, namely for proofing errors that occured in semantic transformation.

Section 4: Technical criteria

Clause II.4.1
Security Principles

In order to be admitted to participate in the CBeHIS according to the process defined under Clause III.1.2.1 of this Agreement, each Contracting Party shall ensure the compliance of its NCPeH with the requirements for confidentiality, integrity, authenticity, availability and non-repudiation according to Regulation 2014/910/EU and Article 32 of Regulation 2016/679/EU.

Clause II.4.2
Traceability, audit and non-repudiation

In order to be admitted to participate in the CBeHIS according to the process defined under Clause III.1.2.1 of this Agreement, each Contracting Party shall ensure the compliance of its NCPeH with the requirements for logs, audit trails and non-repudiation according to Regulation 2014/910/EU and Regulation 2016/679/EU.[44]

[44] It must be analyzed and specified which kind of evidences must be created by which entity for which processing operations.

Chapter III
Governance and rules of procedure[45]

Section 1: Governance and rules of procedure for this Agreement

Clause III.1.1

Signature, entry into force, term and termination

Clause III.1.1.1

Signature

(1) In accordance with Clause I.3, this Agreement shall be open to the participation of National Authorities responsible for NCPeH in Member States of the EU and EFTA[46] that meet the admission criteria as set out by this Agreement and taking into account the documents that are referred to in the Annex.

(2) Applications shall be made in writing to the Governing Body. In case the applicant is not the Ministry responsible for eHealth, a written approval from the Ministry responsible for eHealth shall be provided.

(3) The signature of the Agreement by a Contracting Party means that it accepts unconditionally all criteria set out in this Agreement and taking into account the documents that are referred to in the Annex, depending on which CBeHIS it

[45] During previous eHN LSG meetings representatives of MSs agreed that the process itself should be transparent, easy to follow and should be coordinated by a Governing Body.

[46] Existing EU legislation relevant to the agreement is already considered EEA relevant and binding, as for instance the cross-border healthcare directive and the current directive on data protection is and the coming regulation on data protection will be (the lack of mentioning "EEA relevance" in the Directive 2011/24/EU is a pure mistake in the legislative procedure, but has been amended by succeeding procedural actions in EFTA and the EFTA/EEA participating states).

Even though the EFTA states are not covered by the Brussels I and Rome I regimes when it comes to questions regarding jurisdiction (competent court) and legislation (applicable law), the Lugano convention covers all EFTA states (including Switzerland) and has similar rules to the Brussels I regime.

Therefore, it is proposed to not set up any special provisions for EFTA/EEA states but instead have a general reference to admission criteria that includes EU and EEA states.

When it comes to Switzerland, the situation is less clear. Switzerland is providing cross-border healthcare under the social security regulations (883/2004 EC and 987/2009 EC), but is not bound by the cross-border healthcare directive. Other EU legislation is only applicable if it is part of bilateral agreements between Switzerland and the EU. Therefore there probably needs to be a different procedure and a protocol for Switzerland to be bound by the rules of the agreement and relevant EU acquis. Swiss authorities must be involved in this process and the drafting team has already established contact with the Swiss representatives.

wishes to offer as a Country A and/or Country B. The signing of this Agreement is one prerequisite for the admission in accordance with Clause III.1.2.1

Clause III.1.1.2

Entry into force

(1) This Agreement shall enter into force 14 days following the day on which the third Contracting Party has signed the Agreement.

Clause III.1.1.3

Term and termination

(1) This Agreement shall subsist until it is either replaced by another Agreement or legislative act, or is terminated in accordance with paragraph (2).

(2) This Agreement shall only be terminated if agreed in writing unanimously by the Contracting Parties or if the third last Contracting Party withdraws from the Agreement according to Clause III.1.2.3.

Clause III.1.1.4

Amendment of the Agreement[47]

(1) This Agreement may be amended only in writing. Any Contacting Party may propose amendments to this Agreement by forwarding a proposal for amendment to the Governing Body. Upon receiving such a proposal, the Governing Body shall forward the proposal to the other Contracting Parties.

(2) The Agreement may be amended by the eHN in accordance with the relevant procedure defined in the eHN's Rules of Procedures[48].

[47] During previous eHN LSG meetings representatives of MSs agreed to have a prolonged procedure for amending the AA itself thus creating stability and a swifter process when amending Annexes in order to allow the continuous update of especially technical and semantic criteria that may change more often.

[48] Based on discussions on the 12 October 2016, the request of participants was to have the eHN deciding on amendments of the Agreement itself. The proposal of the drafting team is to create a subgroup within the eHN that contains only the CPs of the AA with equal voting rights. This enables the decision-making to be done by the eHN and solves the problem of eHN members not being equal to CPs (+EFTA). The question of unanimous vs. majority voting must be decided when amending the eHN's RoP.

Therefore, two issues must be discussed and decided upon at a higher political/strategical level:

- **the engagement of EFTA states as CPs in the eHN and also Governing Body**
- **how the eHN/subgroup of the eHN shall decide upon amendments of the Agreement: unanimous vs. majority voting**

Clause III.1.2

Admission, withdrawal and exclusion, dispute resolution

Clause III.1.2.1

Admission:

(1) The Governing Body shall prepare a written proposal for the eHN on the decision on the application for admission to participate in CBeHIS within 9 (nine) months after the application is received by the Governing Body[49].

(2) Each Contracting Party that has signed this Agreement shall be admitted by the eHN to participate in the CBeHIS if the compliance of its NCPeH with the criteria set forth in this Agreement is established, taking into account the relevant processes and criteria defined in the documents that are referred to in the Annex. Further steps of the admission procedure are those agreed by the eHN, taking into account the documents that are referred to in the Annex.

(3) There is no entitlement to admission to participate in CBeHIS. The decision on the application for admission will be sent in writing to the applicant by the eHN. It does not need to be justified. There is no right of appeal or redress.

Clause III.1.2.3

Withdrawal, technical suspension and exclusion[50]

(1) Contracting Parties are entitled to terminate their participation in the Agreement. Withdrawal of a Contracting Party requires a written declaration of the Contracting Party to the Governing Body with a notice period of 4 (four) months. The right to withdraw without notice period for good cause in written form shall remain unaffected. It shall constitute good cause, in particular and without limitation, if

a) the Agreement contradicts national legislation;
b) the continued operation would severely harm the interests of the Contracting Party.

(2) A Contracting Party may accede the Agreement at any time without a readmission ban after the withdrawal of that Contracting Party has become effective.

[49] As the admission process and details of the intitial audit (especially how much time it will take) are not yet known, this provision might be altered. The drafting team still proposes to set a maximum time limit for this process as a safeguard towards the applicants.

[50] **The exclusion of a CP from the Agreement is delegated to the eHN under this Clause. However, one should consider the delegation of this decision to the Governing Body (in the form of the eHN's subgroup comprised of CP only) since otherwise also members of eHN that are no CP would decide upon the exclusion of CP.**

(3) The eHN shall exclude a Contracting Party if the Contracting Party ceases to have legal capacity or ceases to exist. The eHN may exclude a Contracting Party for good cause according to paragraph (4).

(4) The exclusion of the Contracting Party shall take immediate effect as of the date of the decision of the eHN. The Contracting Party must be notified by the eHN of the decision in writing. It shall constitute good cause, in particular and without limitation, if

a. the continued operation of the relevant Contracting Party would harm the aim and main interests of this Agreement;
b. a Contracting Party repeatedly infringes the provisions of this Agreement despite a written reminder by the Governing Body.

(5) In case a Contracting Party does no longer meet the admission criteria stipulated for this Contracting Party in this Agreement, the Governing Body shall set a period of 4 (four) weeks requiring the relevant Contracting Party to fulfil the admission criteria. If these criteria are not fulfilled until the period has expired, the Contracting Party shall be suspended technically from the CBeHIS by the Governing Body upon expiry of the period. The duration of the technical suspension of a Contracting Party from the CBeHIS is indefinite. Technical suspension from the CBeHIS of a Contracting Party ends either when the Governing Body decides that the Contracting Party again meets all the set criteria or the eHN decides upon the exclusion of the Contracting Party from the Agreement.

(6) Immediate interim technical suspension from the CBeHIS by a Contracting Party at its own discretion may be executed only in case this Contracting Party identifies a risk or an incident as defined under Directive 2016/1148/EU[51]. All other Contracting Parties shall be immediately informed thereof by the respective Contracting Party, without prejudice to any obligations under the mentioned Directive.

(7) As of the effective termination of participation in the Agreement, the respective Contracting Party shall no longer be entitled to any rights. Such termination shall not affect commitments entered into or liabilities incurred by the respective Contracting Party prior to such termination.

Clause III.1.2.4

Dispute Resolution

(1) Any dispute between the Parties about the interpretation of any provision of this Agreement or the documents that are referred to in the Annex shall be resolved amicably and informally, as far as possible, pursuant to this Clause.

(2) Prior to the initiation of any formal dispute resolution proceedings including litigation, the Parties shall first attempt to resolve their dispute informally, as follows:

[51] Directive 2016/1148/EU of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union.

a. upon the written request of either Contracting Party to the other, each Contracting Party shall appoint a designated representative for the purpose of endeavouring to resolve such dispute;
b. the designated representatives shall meet as often as either Contracting Party reasonably deems necessary in order to gather and furnish to the other all information with respect to the matter in issue which the Contracting Party believes to be appropriate in connection with its resolution. The designated representatives shall discuss the problem and negotiate with each other in good faith in an effort to resolve the dispute informally;
c. during the course of negotiations, all reasonable requests made by either Contracting Party to the other for non-privileged information, reasonably related to the Agreement, shall be honoured in order that each of the Contracting Parties may be fully advised of the other's position; and
d. the method of endeavouring to resolve the dispute shall be left to the discretion of the designated representatives.

(3) Neither Contracting Party shall commence formal dispute resolution proceedings including litigation, until the earlier of:

a. the Parties' designated representatives as referred to in paragraph (2) jointly concluding that resolution of the dispute through continued negotiation of the matter does not appear likely; or
b. 30 (thirty) Working Days after either Contracting Party's written request under paragraph (2) has been submitted to the other Contracting Party and that other Contracting Party has failed to appoint a designated representative.

(4) If the dispute cannot be resolved by informal dispute resolution, a formal dispute resolution process will be followed.

(5) This Clause shall not constitute a waiver of either Contracting Party's right to institute formal dispute resolution proceedings including litigation in order to avoid the expiration of any applicable limitation periods.

(6) Each Contracting Party must agree to continue performing its obligations under the Agreement while any dispute is being resolved informally, unless and until the Agreement is terminated or in accordance with the final determination of the dispute resolution procedure.

Clause III.1.2.5

Governing body[52]

(1) The Governing Body that is agreed by the eHN shall be responsible for the support of the implementation of this Agreement. It is composed by all Contracting Parties having equal rights in the decision making process.

(2) The structure, functioning and procedures of the Governing Body is described in its Rules of Procedures.

(3) The Governing Body is responsible for, in particular,

a. the coordination of the admission procedure in order to support the eHN;
b. the coordination of amendment procedure of the Agreement in order to support the eHN;
c. coordination of the signing of the Agreement and acting as a depository of all signed versions of this Agreement. It shall supply duly certified copies of this Agreement to each of the Contracting Parties as soon as practicable after the receipt of signed duplicates of this Agreement from all Contracting Parties;
d. the continuous monitoring of the implementation of the Agreement;
e. the coordination of the exclusion of a Contracting Party in order to support the eHN;
f. deciding on the technical suspension of a Contracting Party from the CBeHIS;
g. the coordination of the withdrawal process of a Contracting Party;
h. changing the list of referred documents in the Annex; and
i. other secretariat functions.

[52] The Governing body is needed under and beyond eHDSI:

1. The eHDSI Governance model is currently under revision by the EC based on MS's recommendations.

2. The eHDSI Governance is only applicable until the CEF project is ongoing.

3. The CEF structure will endeavour to engage non participating EU MSs and also EFTA countries but it is yet not known how.

It is also doubtful that these "non-participating" states will have equal rights in the decision making processes, not least as there are several constellations (EU or EFTA / participating in eHDSI with or without CEF funding / not participating at all in eHDSI). Therefore the AA aims for a more stable, permanent structure that seeks alignment and is taking into account the already existing structures and processes and goes beyond CEF funding.

A version: eHN creates a subgroup that is responsible to carry out all tasks of the GB.

B version: as long as eHDSI Governance is operational, the eHMSEG (creating a legal sub-group), the eHOMB and the eHN will act as GB's with well defined and clearly divided responsibilities.

If necessary, a separate non-paper may be elaborated after the eHDSI Governance model is revised by the EC that further analyzes the suggested options, its pros and cons. Until then, the AA will only refer to a GB in general and will only state the functions of the GB.

Section 2: Governance and rules of procedure for the Annex[53]

Clause III.2.1

(1) The list of referred documents in the Annex may be changed by the Governing Body that is agreed by the eHN.

(2) Amendments of the list of referred documents in the Annex are not considered as an amendment of the Agreement.

(3) In case of contradiction between the Clauses of this Agreement and the provisions in the documents listed in the Annex, the Clauses of this Agreement shall prevail.

[53] During previous eHN LSG meetings representatives of MSs agreed to have a prolonged procedure for amending the AA itself thus creating stability and a swifter process when amending Annexes in order to allow the continuous update of especially technical and semantic criteria that may change more often. For achieving this aim, there exist basically the same uncertainties and options as stated in footnote 37 above. However, it is not proposed to involve the eHN (meeting only twice a year on a strategic and political level) in the swift process for changing Annexes.

Annex

1. **Guidelines on Electronic exchange of health data under the Cross-Border Directive 2011/24/EU**

2. **Guideline on an Organisational Framework for eHealth National Contact Point**

3. **Recommendations on Country Guide for eHealth NCP implementation (CEF Preparation)**

4. **Policy Paper on assessment and decision procedures under CEF funding**[54]

5. **Technical criteria for CEF Preparation** (requirements and recommendations, service deployment plan, preparation progress report) **and CEF Deployment** (readiness criteria, initial audit)[55]

6. **Mandatory attributes used by Contracting Parties acting as Country A for the unambiguous identification of patients**

7. **eID specific Framework for eHealth**

8. **Guideline on Interoperability of electronic professional registries**

9. **Governance model for the eHealth Digital Service Infrastructure during the CEF funding**

10. **Rules of Procedures of the eHealth Network**

[54] Title of document not yet decided (by eHN).

[55] To be produced by the eHDSI solution provider/EC SANTE but not yet decided (by eHN).